Remarks

After entry of this Amendment claims 1-23 and 42-43 are pending in the application, claims 44-45 are cancelled. Reconsideration is respectfully requested.

Interview

Applicant thanks the Examiner for the April 18, 2008 telephone interview during which we discussed §112 rejections, claim amendments and the Yang reference. The Amendments and Remarks herein address these issues.

1. Claims 1, 3, 5-9, 11-14 and 42-45 are rejected under 35 USC §112, first paragraph, because the specification, allegedly, does not reasonably provide enablement for any acid, including string [*sic*] acids for pretreating chitin-containing fungal biomass with a mild acidic solution. Applicant traverses.

While Applicants disagree that the referenced claims are not enabled, to further prosecution, the independent claims at issue have been amended to recite "HCl and/or citric acid" in the pretreatment limitations. Accordingly, Applicant requests the rejection be withdrawn.

> Amendment Support: For the amendment to recite HCl and citric acid use for the pretreatment step in claim 1 at (b), claim 42 at (b), and in claim 43 at (b)(i), there is support in the specification at, e.g., p. 16, ll. 5-16. Also see, p. 19, ll. 21-23; p. 20, ll. 18-19; p. 21, ll. 21-24; p. 22, ll. 17-19; p. 25, ll. 5-8.

2. Claims 1-23 and 42-45 are rejected under 35 USC §112, first paragraph, alleging that the specification does not reasonably provide enablement for converting the chitin in the fungal biomass to glucosamine using any acid at various concentrations and pretreating the fungal biomass under any conditions. Applicant traverses.

This issue was discussed with the Examiner, the undersigned counsel for Applicant and inventor Lawrence Fosdick during the Examiner Telephone Interview on April 18, 2008. The conversion of chitin to glucosamine limitations of the rejected claims are herein amended to recite HCl. (The pretreatment enablement rejection is addressed in Item 1 above.)

Amendment Support: For the amendment to recite HCl for the conversion of chitin to glucosamine in claim 1 at (c), claim 15 at (c), claim 20 at (b), and claim 43 at (d), there is support in the specification at, e.g., p. 13, ll. 14-26 and in Examples 1-8.

Further limitation to the claims is not required under §112 to enable the claims for the conversion step because, as discussed below, the claims are sufficiently enabled for one of ordinary skill in the art to practice the conversion step without undue experimentation.

Specifically, the concentration used depends on the other parameters chosen such as temperature, pressure, reaction time and whether or not a pretreatment step will be performed. The specification teaches what concentrations to choose based on particular temperatures, reaction times, and pretreatment(s) performed if any (or what temperatures and reaction times to use for particular chosen acid concentrations) so that persons of ordinary skill in the art can practice the invention without undue experimentation. The specification sets forth many possible combinations with multiple examples, ranges and specifics thereby providing sufficient enablement for one of ordinary skill in the art to choose an acid concentration and other parameters that will cause a conversion of chitin to glucosamine (as well as examples for the pretreatment step that will not convert a substantial amount of chitin to glucosamine if the claimed method includes a pretreatment step). As such, claims 1-23 and 42-43 are sufficiently enabled to meet the requirements under §112. It is important when determining whether the claims are enabled to note the following:

- One does not look to the claims but the specification as to how to practice the invention. MPEP § 2164.08.
- The claims do not need to list every possible parameter. "When analyzing the enabled scope of a claim, the teachings of the specification must not be ignored because claims are to be given their broadest reasonable interpretation that is consistent with the specification." MPEP § 2164.08.
- As required by §112, the specification discloses sufficient information in the form of discussion, examples and ranges for making and using the invention bearing "a reasonable correlation to the entire scope of this claim" per MPEP § 2164.01(b).
- Failure to disclose all methods by which the claimed invention may be made does not render a claim invalid under §112. MPEP § 2164.01(b).

Accordingly, Applicant respectfully requests that the rejection be withdrawn.

3. Claims 20-23 and 45 are rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement as allegedly including subject matter not described in the specification. Applicant traverses.

As to claims 20-23, the Examiner alleges that there is not specification support for the recited acid range of 9% to 20%. Specific support for the lower concentration of 9% is disclosed in the specification as well as concentrations up to the recited upper level of 20%. For example, the specification in Example 7 and in the accompanying Table at p. 25, ll. 3-4 recite examples where 9% HCl was used at a temperature within the recited claim range. In the specification there are disclosed numerous examples at specific concentrations and various ranges up to 20% HCl, such as at p. 13, ll. 14-26 (ranges up to 20% specifically, such as 17-20% at l. 25), Figs. 2 and 3 (17-20%), p. 17, ll. 13-17 (17%), p. 18, ll. 20-21 (4-20%), p. 20, ll. 29-30 (20%), p. 22, ll. 5-7 (20%), and p. 23, ll. 3-5 (19.3%);, p. 24, ll. 27-29 (13%), p. 25, ll. 3-8 (9%, 11%, and 13%). The full range is supported including specific examples at the lower concentration of 9%, the higher concentration of 20% and for concentrations therebetween. Accordingly, Applicant respectfully requests that the rejection be withdrawn.

4. Claims 1-14 and 42-45 are rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner states that it is unclear how pretreatment of fungal biomass without converting chitin to glucosamine and converting fungal biomass to glucosamine can be performed under the same conditions such as, for example, with an acid at a concentration of about 5%. Applicant traverses this rejection.

This rejection is improper for the reasons set forth above in relation to rejections 1 and 2 above and as discussed during the last Examiner's Interview. Further, the claims have been amended to address the Examiner's concerns regarding recited acids. Applicant respectfully requests that the rejection be withdrawn.

5. Claims 20-23 and 42-45 are rejected under 35 USC § 103(a) as allegedly being obvious in view of Yang. Applicant traverses.

Claim 20: Amended claim 20 recites a method of obtaining glucosamine from fungal biomass, including, *inter alia,* reacting the fungal biomass in an acidic solution comprising HCl with an acid concentration of 9% to 20% and at a reaction temperature of from about 90°C to about 160°C and for a reaction period sufficient to convert at least about 50% of the chitin in the fungal biomass to glucosamine and separating the glucosamine from the acidic solution.

Support for the Amendment of Claim 20 to recite converting "at least about 50% of" the chitin in the fungal biomass to glucosamine, is shown on p. 14, ll. 23-26.

Yang neither teaches nor suggests the method of claim 20. Yang teaches a two step process each of which step acts to convert chitin to soluble forms of glucosamine –

A first acid step using **29% HCl at 20°C** (para. 3 of Yang); and

a second with **7.3% HCl at 121°C** ("Results and Discussions – Measurement of Glucosamine" para. 1).

Never does Yang teach or suggest the recited acid concentration (9% to 20%) together with the recited reaction temperature (90-160°C) of claim 20. Accordingly, claim 20 is not anticipated by Yang.

The Examiner asserts, however, that that the Yang reference teaching of the use of 7.3% acid at 121°C versus the recited 9% acid at 90-160°C are sufficiently close that the second Yang step makes the recited 9% acid limitation obvious. Applicant disagrees. In fact, Applicant's specification itself indicates that an acid concentration of 7.3% may not provide the recited level of conversion of chitin to glucosamine even though 9% clearly does – which evidences that the difference between the two values is not an obvious or equivalent variation.

Specifically, as can be seen in the specification at Table 3 (p. 25), a concentration of 6.2% HCl reacted with fungal biomass at 140°C yields less than 20% conversion of chitin to glucosamine. In Example 7 (pp. 24-25), however, it is shown that 9% HCl at 113°C gives a 70% conversion of chitin to glucosamine. The 6.2%, which failed to provide the desired amount of conversion, is closer to the Yang 7.3% than is the 9% presently recited in claim 20. Accordingly, the evidence recited in the present specification itself shows that one of ordinary skill in the art would not have a reasonable expectation that an acid concentration of 7.3% would work as required by the recited claim 20 method – there would be no reasonable expectation of success using a concentration of 7.3% HCl.

Furthermore, the claim 20 method recites use of HCl with a concentration of 9% to 20% at a reaction temperature of from about 90°C to about 160°C for a reaction period sufficient to convert at least about 50% of the chitin in the fungal biomass to glucosamine - the Yang teaching of 7.3% HCl at 121°C cited by the Examiner as making the claim 20 method obvious does not yield a conversion of at least about 50% of the chitin to glucosamine.

More specifically, as set forth in the accompanying §1.132 Declaration of Tzzy-Jan Han, the teaching of Yang that the Examiner cites against the present claim actually achieves less than a 26% conversion of chitin to glucosamine. To achieve a greater conversion value, Yang requires its two acid treatment/conversion steps. Accordingly, this evidence further distinguishes Yang.

Lastly, as mentioned below in regard to claim 43, Yang does not teach or suggest separating the glucosamine from the solution, as recited in claim 20.

For the reasons set forth above, claim 20 is patentable over the art of record and withdrawal of the rejection is respectfully requested.

Claim 21: Claim 21 depending from claim 20 is allowable over Yang for the same reasons as set forth above in relation to claim 20.

Claim 22: Claim 22 recites the method of 20 wherein the reacting of fungal biomass in an acidic solution is performed in a sealed container that allows pressure therein to increase as a result of the reaction. Yang does not teach or suggest use of a sealed container for the reaction or an increased pressure. Rather than increase pressure to aid the conversion of chitin to glucosamine, Yang discloses use of two acid reactions to obtain adequate conversion. Thus, for the reasons set forth above in relation to claim 20, and for this reason as well, claim 22 is allowable over Yang.

Claim 23: Claim 23 recites the method of claim 20 wherein the reaction temperature is from about 105°C or greater and the reaction takes place at a pressure of about 2 atmospheres or greater. As discussed immediately above, Yang does not teach or suggest increasing the pressure to aid the conversion of chitin to glucosamine, but instead discloses use of two conversion acid reactions to obtain conversion. Thus, for the reasons set forth above in relation to claim 20 and for these reasons as well, claim 23 is allowable over Yang

Claim 42: Claim 42 recites in part, pretreating the biomass with an acidic solution at a temperature of from about 60°C to about reflux temperature of a mixture of the acidic solution and biomass to release the proteins, lipids and/or polysaccharides *without converting a significant amount of chitin to glucosamine*. Yang discloses a first step at 20°C (far below the claimed temperature) and the Yang second acid reaction step clearly converts a significant amount of chitin to glucosamine (32% conversion – see the Tzzy-Jan Han Declaration). Accordingly, claim 42 is allowable over Yang.

Furthermore, claim 42 has been amended to recite "wherein a commercial-scale amount of the glucosamine composition is produced." Support for this amendment can be found throughout the specification (the entire aim is to produce glucosamine from biomass on a viable commercial scale), see for example, p. 3, ll. 1-3. This further differentiates Yang. The MPEP §2143.02 II states that while obviousness does not require absolute predictability, at least some degree of predictability is required. There is little predictability (as shown in the §1.132 Declaration filed with the last Amendment) that Yang would be successful on a commercial scale. Accordingly, for this reason as well, claim 42 is allowable over Yang.

Claim 43 recites in part, separating solids from the proteins, lipids and/or polysaccharides in liquid form and treating the separated solids to convert chitin therein to glucosamine. Yang does not separate the solids nor does Yang treat solids that were separated to convert the chitin therein. Yang discloses no such separation as its first acid treatment step and its second acid treatment step are both aimed at converting as much chitin to soluble forms of glucosamine as possible. See, for example, the language in paragraph 8 of Yang stating that the first step in the very concentrated HCl is performed for deacetylation of chitin and the second step treatment with HCl is for depolymerization of chitin. There is no need or desire to separate the solid fungal biomass from proteins, lipids and/or polysaccharides in Yang. Accordingly, for these reasons as well, claim 43 is allowable over Yang.

Respectfully submitted,

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